

EXHIBIT 5
ABDCMDL00269677



February 6, 2018

Ms. Demetra Ashley
Acting Assistant Administrator
Diversion Control Division
U.S. Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152

Dear Ms. Ashley:

As the Drug Enforcement Administration (DEA) is aware, on June 30, 2017, the United States Court of Appeals for the District of Columbia Circuit ("D.C. Circuit") issued its decision in the matter of *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration* ("*Masters*"). The National Association of Chain Drug Stores (NACDS) respectfully requests that DEA promulgate regulations to affected registrants regarding their suspicious order monitoring regulatory obligations in light of the *Masters* decision. We are aware that DEA has been working on regulations to clarify registrants' responsibilities under 21 C.F.R. § 1301.74(b); we believe that the D.C. Circuit's ruling in the *Masters* case necessarily increases the urgency of DEA's promulgation of guidance concerning affected registrants' suspicious order monitoring responsibilities.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate 40,000 pharmacies, and NACDS' nearly 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 152,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 20 countries. Please visit nacds.org.

We are concerned that the D.C. Circuit may have interpreted the suspicious order reporting requirement under 21 C.F.R. § 1301.74(b) differently than DEA has interpreted the regulation in the past or intended to do so in the future. Moreover, DEA field division offices across the country may each have their own interpretation of the *Masters* decision, which could significantly affect enforcement of this regulation.

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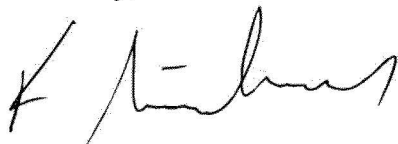
While some distributors may identify suspicious orders through a statistically driven threshold incursion system, other distributors may operate an "Order of Interest" monitoring system to assist them in meeting reporting obligations set forth in 21 C.F.R. §1301.74(b). In an "Order of Interest" system, a statistical algorithm identifies "Orders of Interest" that may require additional evaluation. After additional evaluation, those orders may be cleared as "not suspicious," or regarded as "suspicious" and reported to DEA. Based on the *Masters* decision, NACDS poses the following questions:

(1) Whether all orders identified as "Orders of Interest" must now be reported to DEA as "suspicious"?

(2) Is there a "middle ground" that DEA perceives may exist that permits both statistically driven threshold systems and "Order of Interest" systems, such that registrants operating the latter system need not prematurely or automatically deem an order as "suspicious" when the order is merely flagged for further review?

We respectfully request that DEA address these questions and concerns as soon as reasonably possible to avoid confusion among registrants and to provide clear guidance to industry and DEA field offices. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'K. Nicholson', written over a horizontal line.

Kevin N. Nicholson, R.Ph., J.D.
Vice President
Public Policy and Regulatory Affairs